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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,318	02/14/2002	Cheryl M. Hayward	PC11022AADO	2855

7590 04/22/2004

Gregg C. Benson
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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,318

Applicant(s)

HAYWARD ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 10-22, 24-36 and 42-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-9, 23 and 37-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20040519</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/14/2002</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-27 and 37-41 drawn to compounds of formula I, and compositions thereof, in the response mailed 23 October 2003 is acknowledged. Applicant election of the species 2-(3-(2-[1-heptyl-3-(4-isopropyl-phenyl)-ureido]-ethyl)-phenoxy)-2-methylpropionic acid is also acknowledged. Claims 1-3, 7-9, 23 and 37-41 are readable thereon. Since prior art that renders the elected specie obvious has been found (See below), claims 4-6, 10-22, 24-36 and 42-47 are held withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

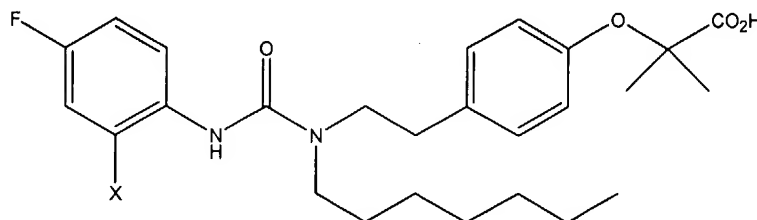
U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 7-9, 23 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franzmann et al (WO 92/10468-A1 06-1992).

Instantly claimed are compounds of Formula I having the following values for variable groups: Z= carboxyl; B = O; R₁, R₂=CH₃; R₅, R₆=H; R₃=C₆H₁₃; W = -N(H)-; A= mono- or difluoro-substituted phenyl and pharmaceutical compositions thereof.

Franzmann teaches (Page 26, lines 1-2) the PPAR α agonist of formula I:



where X is fluorine. Franzmann further teaches (Page 26, line 7 – page 30, end) pharmaceutical compositions of the compound of formula I. Franzmann teaches (Page 6, 2nd full paragraph) that these compounds can be employed for the treatment of atherosclerosis.

The difference between the instantly claimed compounds and those taught by Franzmann is that the two groups attached to the oxy-substituted aromatic ring have

a 1,4- relationship in the compounds of Franzmann while those in the instant case have a 1,3- orientation. The instant compounds are therefore related as isomers about an aromatic ring to those taught by Franzmann.

The Examiner further notes that Franzmann teaches (Page 2, line 4-page 4, end) a genus of compounds which contains the compound isomeric to the elected species as well and specifically teaches (Page 25, compound 87, lines 5-6) isopropyl substitution about the aromatic ring corresponding to instant variable A. This teaching provides sufficient guidance to one of ordinary skill in the art for selection of the isopropyl group for this variable.

One of ordinary skill in the art would have been motivated to make the instant compounds by expectation that the instant compounds, because of their close structural similarity, would have similar properties to those of Franzmann. There would therefore have been a reasonable expectation for success.

Thus the instantly claimed compounds and their pharmaceutical compositions would have been obvious to one of ordinary skill in the art.

4. Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franzmann et al (WO 92/10468-A1 06-1992) as applied to Claims 1-3, 7-9, 23 and 37-38 above and further in view of Jorgenson et al (US 6,562,807-B2 05-2003).

Instantly claimed are pharmaceutical compositions comprising a compound of Formula I and a second active agent such as the HMG-CoA reductase inhibitor lovastatin.

Franzmann teaches (Page 38, claim 15(b)) that the compounds of formula I may be employed with a second physiologically active agent.

The difference between the compositions taught by Franzmann and those instantly claimed is that Franzmann is silent with regard to the nature and identity of the second physiologically active agent while the use of a HMG CoA reductase inhibitor is instantly claimed.

Jorgenson, however, teaches (Column 25, line 62-column 26, line 4) compounds and methods for the treatment of atherosclerosis. Jorgenson further teaches (Column 27, line 27- column 28, line 31) the use of PPAR agonists and HMG-CoA reductase inhibitors such as lovastatin in pharmaceutical compositions.

Thus one of ordinary skill in the art seeking to follow the suggestion of Franzmann to use his PPAR α agonist compounds of formula I in combination therapies would have been compelled to seek guidance elsewhere in the art. Jorgenson provides the required guidance in his teaching of the use of PPAR α agonists and lovastatin. Because Jorgenson explicitly teaches the instantly claimed combinations, there would therefore have been a reasonable expectation for success.

Thus the instantly claimed pharmaceutical compositions would have been obvious to one of ordinary skill in the art.

Conclusion


5. Claims 1-47 are pending. Claims 1-3, 7-9, 23 and 37-41 are rejected. Claims 4-6, 10-22, 24-36 and 42-47 are held withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Paul Zucker', is written over a horizontal line.

Paul A. Zucker, Ph. D.
Patent Examiner
Technology Center 1600